

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

**CHAMBERS OF  
JOEL SCHNEIDER  
UNITED STATES MAGISTRATE JUDGE**

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**LETTER ORDER  
ELECTRONICALLY FILED**

August 13, 2012

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**Re: Sciele Pharma, Inc., et al. v. Lupin, LTD, et al.  
Civil No. 09-37 (RBK/JS)  
Shionogi Pharma Inc. et al v. Mylan Inc. et al.  
Civil No. 10-135 (RBK/JS)**

Dear Counsel:

This letter addresses Shionogi's request that the Court Order Mylan to produce unexpired samples of its ANDA product. Mylan agrees to produce the samples but the parties dispute when this should be done. Shionogi wants the samples as soon as they are manufactured. Mylan agrees to produce the samples but only if it "launches" and then after the launch.<sup>1</sup> This issue was raised and argued at the July 13, 2012 hearing. The Court received the parties' recent letter briefs (D.I. 506, 514) and exercises its discretion not to conduct any additional oral argument. For the reasons to be discussed, Shionogi's request is DENIED.

It is well established that matters of docket control and the

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1. The Court has no present understanding if and when Mylan will "launch."

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conduct of discovery are committed to the sound discretion of a Magistrate Judge. Gerald Chamales Corp. v. Oki Data Americas, Inc., 247 F.R.D. 453, 454 (D.N.J. 2007). Further, pursuant to Fed. R. Civ. P. 26(c)(1)(B), a court may issue an order specifying terms, including time and place, for disclosure or discovery. For the reasons to be discussed, the Court is satisfied that it is appropriate for Mylan to produce its samples promptly after it launches, and not before. This is consistent with Rule 26(e) which requires a "timely" supplement to an incomplete or inaccurate disclosure or discovery response.<sup>2</sup> The Federal Rules do not require a party to immediately supplement its discovery responses the moment new responsive information becomes available. If Mylan decides to launch, the Court assumes that the time it begins to manufacture will be sufficiently close to the launch date as to render its production of new samples timely.

Although not determinative, the pre-suit launch issue is not irrelevant to the Court's ruling. All parties acknowledge there is no legal authority to compel Mylan to give advance notice if and when it will launch. The Court is not inclined to issue an Order that permits Shionogi to get through the "back door" what it cannot get through the "front door."

Shionogi argues it needs immediate production of Mylan's samples to prepare its preliminary injunction papers. However, there is no certainty that the motion will be filed. Even if the motion is filed, courts routinely handle preliminary injunction motions without pre-launch test results.

Significantly, Shionogi has not cited a single instance where a court ordered a party to produce pre-launch samples of its product so that pre-launch testing could be done in the event a preliminary injunction motion was eventually filed. The case law Shionogi cites is not on point. Robbins & Myers, Inc. v. J. M. Huber Corp., 274 F.R.D. 63 (W.D.N.Y. 2011) (addressing the duty to produce documents that were not in existence when an original response was served); Adams v. Teck Cominco Alaska Inc., 231 F.R.D. 578 (D. Alaska 2005) (addressing whether documents relied upon to support a summary judgment motion should be barred if they were not produced in discovery); Zoltek Corp., v. U.S., 71 Fed. Cl. 160 (Fed. Cl. 2006) (government violated discovery rules by failing to disclose relevant documents until three years after receiving them); AVX

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2. For purposes of this analysis only, the Court credits Shionogi's argument that after Shionogi made it known that the samples Mylan produced "expired," Mylan's production was rendered "incomplete" within the meaning of Rule 26(e). Thus, Shionogi did not have to serve a new request for unexpired samples pursuant to Rule 34. Mylan, of course, has the right to object to producing new samples. See Rule 26(c).

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Corp. v. Cabot Corp., 251 F.R.D. 70 (D. Mass. 2008) (striking portion of a supplemental answer to a damages interrogatory served after the close of fact discovery).

Accordingly, for all the foregoing reasons, Shionogi's request that Mylan produce unexpired samples of its ANDA product when manufacturing begins is DENIED. In accordance with Rule 26(e), and assuming Mylan launches, Mylan shall timely produce unexpired samples after it launches.

Very truly yours,

*s/ Joel Schneider*

JOEL SCHNEIDER  
United States Magistrate Judge

JS:jk

cc: Hon. Robert B. Kugler